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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,233	06/11/2001	Jennifer L. Hillman	PF-0579 USN	5403

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,233	HILLMAN ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8, 12, 13, and 15, drawn to a substantially purified polypeptide (claims 1 and 2), an isolated and purified polynucleotide encoding the polypeptide of claim 1 (claims 3-6), an expression vector comprising at least a fragment of the polynucleotide of claim 3 (claim 12), and a host cell comprising the expression vector (claim 13), and a pharmaceutical composition comprising the polypeptide of claim 1 (claim 15), and a method for detecting a polynucleotide (claims 7 and 8).

Group II, claims 9-11, drawn to an isolated and purified polynucleotide.

Group III, claim 14, drawn to a method for producing a polypeptide.

Group IV, claims 16-18, drawn to a purified antibody which specifically binds to the polypeptide of claim 1 (claim 16), a purified agonist of the polypeptide of claim 1 (claim 17), and a purified antagonist of the polypeptide of claim 1 (claim 18).

Group V, claims 19, drawn to a method for treating or preventing a disorder associated with decreased expression or activity of RNAAP.

Group VI, claim 20, drawn to a method for treating or preventing a disorder associated with decreased expression or activity of RNAAP.

2. The inventions listed as Groups I to VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because the technical feature linking Groups I and II is not special. For example, an isolated and purified polynucleotide of Group II (ie., a fragment of SEQ ID No: 26) is not a contribution over the prior art wherein SEQ ID NO: 2 of US Patent No. 5,525,487 comprising poly(A) tail read claim 9.

Groups I to III do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the method required for Group I is not required for Group III while the method required for Group III is not required for Group I.

Groups I to IV do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the method required for Group I is not required for Group IV while the antibody required for Group IV is not required for Group I.

Groups I to V do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the method required for Group I is not required for Group V while the method required for Group V is not required for Group I.

Groups I to VI do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the method

required for Group I is not required for Group VI while the method required for Group VI is not required for Group I.

Group II and Groups III, IV, V, and VI do not relate to a single general inventive concept under PCT Rule 13.1 because the technical feature linking Group II and Groups III, IV, V, and VI is not special. For example, an isolated and purified polynucleotide of Group II (a fragment of SEQ ID No: 26) is not a contribution over the prior art wherein SEQ ID NO: 2 of US Patent No. 5,525,487 comprising poly(A) tail read claim 9.

Groups III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the method required for Group III is not required for Group IV while the antibody required for Group IV is not required for Group III.

Groups III and V do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the method required for Group III is not required for Group V while the method required for Group V is not required for Group III.

Groups III and VI do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the method required for Group III is not required for Group VI while the method required for Group VI is not required for Group III.

Groups IV and V do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the

antibody required for Group IV is not required for Group V while the method required for Group V is not required for Group IV.

Groups IV and VI do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the antibody required for Group IV is not required for Group VI while the method required for Group VI is not required for Group IV.

Groups V and VI do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the method required for Group V is not required for Group VI while the method required for Group VI is not required for Group V.

3. Sequence Election Requirement Applicable to Groups I to VI .

The polynucleotide and polypeptide products in Groups I to VI read on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Although the polynucleotides and polypeptides are related as the claimed polynucleotide is asserted to encode the claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein as evidenced by the method in Group I. Therefore, applicant must further elect a single SEQ ID NO. (See MPEP 803.04). Applicant is advised that examination will be restricted to only elected SEQ ID NO. and should not to be construed as a species election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (703)872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
July 28, 2004

FRANK LU
PATENT EXAMINER